K062105

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Submitter's name:	Diazyme Laboratories
Submitter's address:	3550 General Atomics Court San Diego, CA 92121 USA APR 2 3 2007
Name of Contact Person:	Dr Abhijit Datta Diazyme Laboratories 3550 General Atomics Court San Diego, CA 92121 Phone: 858-455-4762 Fax: 858-455-2120
Date the Summary was Prepared:	Revised on March 27, 2007
Name of the Device	In Vitro Diagnostic Creatinine Test System
Trade Name:	Diazyme Creatinine Liquid Reagents Assay Diazyme Creatinine Control
Common/Usual Name	Creatinine Test System
Device Classification Name	Enzymatic Method, Creatinine Single (specified) analyte controls (assayed and unassayed
Product code:	JFY, JJX
Submission Type	510k
Regulation Number	862.1225, 862.1660
Device Class	II (Enzymatic Method, Creatinine) I (Single (specified) analyte controls (assayed and unassayed)
Predicate Device:	For the Creatinine test system, we are claiming equivalence [807.92(a) (3) to CREATININE PLUS (k003261) manufactured by Roche Diagnostics GmbH, D-68298 Mannheim, Germany. For the Diazyme Creatinine control which is a single (specified) analyte controls (assayed), the predicate is k063206

R 3/29/07

Substantial Equivalence Information

1. **Predicate device name(s):**

   Roche Creatinine Plus

   Dimension Vista Protein Control L, M, H

2. **Predicate 510(k) number(s):**

   k003261, k063206

3. **Comparison with predicate:**

Indications for Use

Diazyme Creatinine Liquid Reagents Assay	Roche Creatinine plus test	Equivalency
Diazyme Creatinine Liquid Reagents Assay, in conjunction with Diazyme Creatinine Calibrator, is intended for the quantitative determination of creatinine in serum and urine. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes. For *in vitro* diagnostic use only.	For the quantitative in vitro determination of creatinine in human serum or urine.	Same

Principle

Diazyme Creatinine Liquid Reagents Assay	Roche Creatinine plus test	Equivalency
The enzymatic assay for creatinine involves a series of coupled enzymatic reactions including creatininase enzymatic conversion of creatinine into the product creatine which itself is converted to sarcosine by creatine amidinohydrolase (creatinase), followed by oxidation of sarcosine by sarcosine oxidase (SOD), producing hydrogen peroxide. In the presence of peroxidase (POD), the hydrogen peroxide is quantified at 550 nm by the formation of a colored dye. Any endogenous creatine present in the sample is removed by creatinase and sarcosine oxidase during preincubation.	The enzymatic method is based on the established determination of sarcosine after conversion of creatinine with the aid of creatininase, creatinase, and sarcosine oxidase. The liberated hydrogen peroxide is measured via a modified Trinder reaction. Endogenous creatine is metabolized with the addition of R1 to the sample.	Same

Test Objective

Diazyme Creatinine Liquid Reagents Assay	Roche Creatinine plus test	Equivalency
For the quantitative in vitro determination of creatinine in human serum or urine.	For the quantitative in vitro determination of creatinine in human serum or urine.	Same

Type of Test

Diazyme Creatinine Liquid Reagents Assay	Roche Creatinine plus test	Equivalency
Quantitative	Quantitative	Same

Specimen Type

Diazyme Creatinine Liquid Reagents Assay	Roche Creatinine plus test	Equivalency
Human serum or urine.	Human serum or urine.	Same

Product Type

Diazyme Creatinine Liquid Reagents Assay	Roche Creatinine plus test	Equivalency
Calibrator, Controls, Reagent, Instrument	Calibrator, Controls, Reagent, Instrument	Same

Performance Comparison

Diazyme Creatinine Liquid Reagents Assay	Roche Creatinine plus test	Equivalency
Recovery: **Average of 102.6%** Reportable Range: Serum: **0.14- 13.56mg/dL (12–1200 µmol/L)** Urine: **0.14-141.25 mg/dL (12–12500 µmol/L)** Precision/Serum: Within Run: **0.1% 21.1%** Total: **1.4%–3.0%** Precision/Urine: Within Run: **0.31%–0.46%** Total: **0.61%–2.64%** Accuracy/Serum: Correlation Coefficient: **0.9981** Slope/Intercept: **y = 0.9467x + 0.0643** Accuracy/Urine: Correlation Coefficient: **0.9969** Slope/Intercept: **y = 1.005x – 0.2979**	Recovery: **Average of 105.0%** Reportable Range: Serum/Plasma: **2.7–2652 µmol/L** Urine: **27–35360 µmol/L** Precision/Serum: Within Run: **0.7%–0.9%** Between Run: **1.6%–2.5%** Precision/Urine: Within Run: **0.8%–1.0%** Between Run: **2.1%–3.7%** Accuracy/Serum: Correlation Coefficient: **0.999** Slope/Intercept: **y = 0.989x + 0.036** Accuracy/Urine: Correlation Coefficient: **0.999** Slope/Intercept: **y = 0.999x + 0.037**	Similar

Control Comparison

Diazyme Creatinine Control	Dimension Vista Protein Control L, M, H	Equivalency
Liquid form	Liquid form	Same
Analyte specific Creatinine constituent	Analyte specific, C3, C4, Homocysteine, IGA, IGG, IGM and prealbumin constituents	Same
Traceable to purified Creatinine -NIST SRM 914a standard	Traceable to purified S-adenosyl homocysteine standard	Same

Rationale for Considering the Device Substantially Equivalent to Devices Approved for Inter-state Commerce

Roche Creatinine plus test method (k003261) was selected for comparing serum and urine samples with to the results generated by Diazyme Creatinine Liquid Reagents Assay. Detailed performance characteristics and comparison analysis are given in this filing and demonstrate substantial equivalence to predicate device that is currently being legally marketed.

The Diazyme Creatinine Liquid Reagents Assay is similar to the approved predicate test. The minor differences in the performances of the tests should not affect the safety and effectiveness of the Diazyme Creatinine Liquid Reagents Assay and offers users a rapid device to measure creatinine in human serum.

In summary, the dissimilar features between the Diazyme Creatinine Liquid Reagents Assay and devices currently legally marketed do not affect the safety or effectiveness of the device. This is supported by the accuracy data comparing serum and urine sample values obtained using the Diazyme Creatinine Liquid Reagents Assay with those obtained using the predicate device, Roche Creatinine plus test (k003261). Comparison analysis presented in this 510k submission together with the stability data also demonstrates that the Diazyme Creatinine control is substantially similar to the legally marketed device Dimension Vista Control (k063206).

Description of the Device

This enzymatic assay for creatinine involves a series of coupled enzymatic reactions including creatininase enzymatic conversion of creatinine into the product creatine, which itself is converted to sarcosine by creatine amidinohydrolase (creatinase), followed by oxidation of sarcosine by sarcosine oxidase (SOD) producing hydrogen peroxide. In the presence of peroxidase (POD) the hydrogen peroxide is quantified at 550nm by the formation of a colored dye.

$$\text{Creatinine} + H_2O \xrightarrow{\text{Creatininase}} \text{Creatine}$$

$$\text{Creatine} + H_2O \xrightarrow{\text{Creatinase}} \text{Sarcosine} + \text{Urea}$$

$$\text{Sarcosine} + H_2O + O_2 \xrightarrow{\text{SOD}} \text{Formaldehyde} + \text{Glycine} + H_2O_2$$

$$2H_2O_2 + \text{4-AA} + \text{TOOS} \xrightarrow{\text{POD}} 4H_2O + \text{Quinone dye } (\lambda \text{ max } 556)$$

Intended Use of the Device:

Diazyme Creatinine Liquid Reagents Assay, in conjunction with Diazyme Creatinine Calibrator, is intended for the quantitative determination of creatinine in serum and urine. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes. For *in vitro* diagnostic use only

Diazyme Creatinine Control is an assayed QC material for use in quantitative *in vitro* diagnostic determination of creatinine in human serum and urine. It is intended as a reference sample for monitoring the Diazyme Creatinine Liquid Reagents Assay for gross systematic errors. For *in vitro* diagnostic use only.

Performance Characteristics

Diazyme Creatinine Liquid Reagents Assay is a two-reagent (R1 / R2) based kinetic assay system. The results are obtained in 10 minutes by measuring absorbance at 550nm. On line pretreatment removes endogenous creatine. The assay has a wide measuring range of 0.14-13.56 mg/dL (12-1200 μmol/L) for Serum samples and 0.14 – 141 mg/dL (12 to12500 μmol/L) for Urine samples. The assay offers excellent precision as shown in the tables below:

Serum Testing	**0.75 mg/dL (66.3 μM)**	**1.41 mg/dL (125 μM)**	**3.91 mg/dL (346 μM)**	**10.28 mg/dL (908.7 μM)**
Within-Run Precision	$C_V\% = 2.1\%$	$C_V\% = 1.1\%$	$C_V\% = 0.7\%$	$C_V\% = 0.1\%$
Total Precision	$C_V\% = 3.0\%$	$C_V\% = 1.9\%$	$C_V\% = 1.4\%$	$C_V\% = 1.4\%$

Urine Testing	**30 mg/dL (2652 μM)**	**87.13 mg/dL (7711 μM)**	**196.70 mg/dL (17407 μM)**
Within-Run Precision	$C_V\% = 0.36\%$	$C_V\% = 0.31\%$	$C_V\% = 0.46\%$
Total Precision	$C_V\% = 2.64\%$	$C_V\% = 0.76\%$	$C_V\% = 0.61\%$

In method comparison studies, samples tested with Diazyme Creatinine Liquid Reagents Assay showed good correlation with Roche Creatinine plus (k003261) with correlation coefficients of 0.99 for both serum samples and urine samples. The average analytical recoveries were 97.8% to 109.4% for 11 creatinine serum samples and 97.0% to 104.3% for 22 creatinine urine samples.

We have conducted interference studies by spiking the substances to be tested to pooled human serum and urine, and found little interference at the indicated concentrations.

Serum		**Urine**	
Substance	**Concentration**	**Substance**	**Concentration**
Triglycerides	1000 mg/dL	Triglycerides	1000 mg/dL
Ascorbic acid	10 mmol/L	Ascorbic acid	10 mmol/L
Bilirubin	40 mg/dL	Bilirubin	40 mg/dL
Bilirubin Conjugated	30 mg/dL	Bilirubin Conjugated	40 mg/dL
Hemoglobin	500 mg/dL	Hemoglobin	1000 mg/dL

Conclusion: Comparison analysis presented in this 510k submission filing in the comparison section, together with linearity, precision and interference and other detailed studies, demonstrates that the Diazyme Creatinine Liquid Reagents Assay has excellent accuracy and is safe and effective. There is no significant deviation between the results obtained by Diazyme Creatinine Liquid Reagents Assay and the legally marketed predicate device (k003261) when testing clinical patient samples and is therefore substantially similar. Comparison analysis presented in this 510k submission together with the stability data demonstrates that the Diazyme Creatinine control is substantially similar to legally marketed device (k063206).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Diazyme Laboratories
c/o Dr. Abhijit Datta
Associate Director
3550 General Atomic Court
San Diego, CA 92121

APR 2 3 2007

Re: k062105
Trade/Device Name: Diazyme Creatinine Liquid Reagents Assay
Diazyme Creatinine Control
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine Test System
Regulatory Class: Class II
Product Code: JFY, JJX
Dated: March 19, 2007
Received: March 21, 2007

Dear Dr. Datta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
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Enclosure

Indications for Use

510(k) Number: k062105

Device Name: Diazyme Creatinine Liquid Reagents Assay
Diazyme Creatinine Control

Indications for Use: Diazyme Creatinine Liquid Reagents Assay, in conjunction with Diazyme Creatinine Calibrator, is intended for the quantitative determination of creatinine in serum and urine. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes. For *in vitro* diagnostic use only.

Diazyme Creatinine Control is an assayed QC material for use in quantitative *in vitro* diagnostic determination of creatinine in human serum and urine. It is intended as a reference sample for monitoring the Diazyme Creatinine Liquid Reagents Assay for gross systematic errors. For *in vitro* diagnostic use only.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K062105